



Sheet 1 of 12

FORM PTO-1449
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
51271/35.1 USAPPLICATION NO.
10/632,645

INFORMATION DISCLOSURE CITATION

Title: **ADENO-ASSOCIATED VECTOR COMPOSITIONS FOR
EXPRESSION OF FACTOR VIII**

APPLICANT - Couto, et al.

FILING DATE-
August 1, 2003

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
PV	1	4,757,006	Jul, 12, 1988	Toole, Jr. et al.			Oct. 28, 1983
	2	4,886,876	Dec. 12, 1989	Zimmerman et al.			Apr. 13, 1987
	3	5,004,803	Apr. 2, 1991	Kaufman et al.			Nov. 14, 1988
	4	5,045,455	Sept. 3, 1991	Kuo et al.			June 14, 1990
	5	5,112,950	May 12, 1992	Meulien et al.			June 26, 1991
	6	5,139,941	Aug. 18, 1992	Muzyczka et al.			Oct. 25, 1991
	7	5,149,637	Sept. 22, 1992	Scandella et al.			Sept. 20, 1990
	8	5,171,844	Dec. 15, 1992	Van Ooyen et al.			June 10, 1988
	9	5,173,414	Dec. 22, 1992	Lebkowski et al.			Oct. 30, 1990
	10	5,422,260	June 6, 1995	Kaufman et al.			May 15, 1992
	11	5,451,521	Sept. 19, 1995	Kaufman et al.			Dec. 9, 1986
	12	5,595,886	Jan. 21, 1997	Chapman et al.			Dec. 3, 1993
	13	5,563,045	Oct. 8, 1996	Pitman et al.			Sept. 14, 1993
	14	5,587,310	Dec. 24, 1996	Kane et al.			July 11, 1994
	15	5,622,856	Apr. 22, 1997	Natsoulis			Aug. 3, 1995
PR	16	5,633,150	May 27, 1997	Wood et al.			Oct. 9, 1990

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PR	17	5,661,008	Aug. 26, 1997	Almstedt et al.			June 5, 1995
	18	5,668,108	Sep. 16, 1997	Capon et al.			May 23, 1995
	19	5,681,746	Oct. 28, 1997	Bodner et al.			Dec. 30, 1994
	20	5,693,499	Dec. 2, 1997	Yonemura et al.			July 18, 1994
	21	5,720,720	Feb. 24, 1998	Laske et al.			March 15, 1996
	22	5,789,203	Aug. 4, 1998	Chapman et al.			June 27, 1994
	23	5,858,351	Jan. 12, 1999	Podsakoff et al.			Jan. 18, 1996
PR	24	5,846,528	Dec. 8, 1998	Podsakoff et al.			Jan. 16, 1997

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	PUBLICA- TION DATE	COUNTRY / PATENT OFFICE	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
PR	25	WO 87/07144	Dec. 3, 1987	WTH PCT				
	26	WO 91/07490	May 30, 1991	PCT				
	27	WO 91/09122	June 27, 1991	PCT				
	28	WO 92/01070	Jan. 23, 1992	PCT				
	29	WO 92/08981	May 29, 1992	PCT				
	30	WO 92/16557	Oct. 1, 1992	PCT				
	31	WO 93/03367	Feb. 18, 1993	PCT				
PR	32	WO 93/03769	Mar. 4, 1993	WTH PCT				

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PV	33	WO 94/11503	May 26, 1994	PCT				
	34	WO 96/21035	July 11, 1996	PCT				
	35	WO 97/03195	Jan. 30, 1997	PCT				
	36	EP 0 160 457	Jan. 16, 1991	EP				
	37	EP 0 162 067	July 15, 1992	EP				
	38	EP 0 182 448	May 28, 1986	EP				
	39	EP 0 220 618	Oct. 16, 1986	EP				
	40	EP 0 232 112	Dec. 1, 1993	EP				
	41	EP 0 500 734	Feb. 11, 1998	EP				
	42	EP 0 506 757	Aug. 26, 1998	EP				
	43	EP 0 533 862	Oct. 27, 1999	EP				
	44	EP 0 670 332	Sept. 6, 1995	EP				
	45	EP 0 672 138	Sept. 20, 1995	EP				
	46	EP 0 786 474	July 30, 1997	EP				
	47	EP 0 795 021	Sept. 17, 1997	EP				
h-	48	EP 0 847 057	Oct. 28, 1998	EP				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication, etc.)

PV	49	Aiello et al., "Adenovirus 5 DNA Sequences Present and RNA Sequences Transcribed in Transformed Human Embryo Kidney Cells (KEY-Ad-5 or 293) <i>Virology</i> , 94:460-469 (1979);
PV	50	Antonarakis et al., "Molecular Genetics of Hemophilia A in Man (Factor VIII Deficiency)," <i>Mol Biol. Med.</i> , 4:81-94 (1987);

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51	Berns, "Parvoviridae and Their Replication," in Fields and Knipes (eds.), <i>Fundamental Virology</i> , 2 nd Ed., pp. 817-837 (1991);
52	Boshart et al., "A Very Strong Enhancer is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <i>Cell</i> 41:521-530 (1985);
53	Buller et al., "Herpes Simplex Virus Types 1 and 2 Completely Help Adenovirus-Associated Virus Replication," <i>J. Virol.</i> , 40:241-247 (1981);
54	Capecchi, "High Efficiency Transformation by Direct Microinjection of DNA into Cultured Mammalian Cells," <i>Cell</i> 22:479-488 (1980);
55	Carter, "Adeno-Associated Virus Helper Functions," in <i>CRC Handbook of Parvoviruses</i> Vol. I (P. Tijssen, ed.), pp. 533-539 (1990);
56	Carter, "Adeno-associated virus vectors," <i>Curr. Opin. Biol.</i> , 3:533-539 (1992);
57	Chu et al., "SV40 DNA transfection of cells in suspension; analysis of the efficiency of transcription and translation of T-antigen," <i>Gene</i> 13:197-202 (1981);
58	Costa and Grayson, "Site-directed mutagenesis of hepatocyte nuclear factor (HNF) binding sites in the mouse transthyretin (TTR) promoter reveal synergistic interactions with its enhancer region," <i>Nucl. Acids, Res.</i> , 19:4139-4145 (1991)
59	Costa et al., "Transcriptional Control of the Mouse Prealbumin (Transthyretin) Gene: Both Promoter Sequences and a Distinct Enhancer Are Cell Specific," <i>Mol. Cell. Biol.</i> , 6:4697 (1986)
60	Davis et al., <i>Basic Methods in Molecular Biology</i> , Elsevier (1986) (Title and Copyright Pages Only);
61	Dijkema et al. "Cloning and Expression of the chromosomal immune interferon gene of the rat," <i>EMBO J.</i> 4:761-767 (1985);
62	Edge, "Total Synthesis of a Human Leukocyte Interferon Gene," <i>Nature</i> 292:756-761 (1981);
63	Felgner et al., "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc Natl. Acad. Sci U.S.A.</i> 84: 7413-7417 (1987);
64	Ganz et al, "Human factor VIII from heparinized plasma; purification and characterization of a single-chain form," <i>Eur. J. Biochem.</i> , 170:521-528 (1988);
65	Glover et al. (ed.), <i>DNA Cloning: A Practical Approach</i> , Vols. I and II, Oxford; New York: IRL Press (1995) (Title and Copyright Pages Only)
66	Gorman et al., "The Rous sarcoma virus long terminal repeat is a strong promoter when introduced into a variety of eukaryotic cells by DNA-mediated transfection," <i>Prod. Natl. Acad. Sci USA</i> 79: 6777-6781 (1982);
67	Graham and Van der Eb, "A New Technique for the Assay of Infectivity of Human Adenovirus 5 DNA," <i>Virol.</i> , 52: 456-467 (1973);
68	Graham et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5," <i>J. Gen. Virol.</i> , 36:59-72 (1977);
69	Herzog, et al., "Long-term correction of canine hemophilia B by gene transfer of blood coagulation factor IV mediated by adeno-associated viral vector," <i>Nature Med.</i> , 5:56-63 (1999);
70	Janik et al., "Locations of adenovirus genes required for the replication of adenovirus-associated virus," <i>Proc. Natl. Acad. Sci. USA</i> 78:1925-1929 (1981);

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71	Jay et al., "Chemical Synthesis of a Biologically Active Gene for Human Immune Interferon- γ ," <i>J Biol. Chem.</i> 259:6311-6317 (1984);
72	Kaufman et al., "Synthesis, Processing and Secretion of Recombinant Human Factor VII Expressed in Mammalian Cells," <i>J. Biol. Chem.</i> , 263:6352-6362 (1988);
73	Kaufman, "Biological Regulation of Factor VIII Activity," <i>Ann. Rev. Med.</i> , 43:325-339 (1992);
74	Kim et al., "Use of the human elongation factor 1 α promoter as a versatile and efficient expression system," <i>Gene</i> 91:217-223 (1990);
75	Klein et al., "High-velocity microprojectives for delivering nucleic acids into living cells," <i>Nature</i> 327:70-73 (1987);
76	Kotin, "Prospects for the Use of Adeno-Associated Virus as a Vector for Human Gene Therapy," <i>Hum. Gen. Ther.</i> , 5:793-801 (1994);
77	Lebkowski et al., "Adeno-Associated Virus: a Vector System for Efficient Introduction and Integration of DNA into a Variety of Mammalian Cell Types," <i>Mol. Cell Biol.</i> , 8:3988-3996 (1988);
78	Lind et al., "Novel forms of B-domain-deleted recombinant factor VIII molecules; construction and biochemical characterization," <i>Eur. J. Biochem.</i> , 232:19-27 (1995);
79	Maniatis et al., "Regulation of Inducible and Tissue-Specific Gene Expression," <i>Science</i> 236: 1237-1244 (1987);
80	Mannino et al., Liposome Mediated Gene Transfer," <i>BioTechn.</i> , 6:682-690 (1988);
81	Matsushita et al., "Adeno-associated virus vectors can be efficiently produced without helper virus," <i>Gene Ther.</i> , 5:938-945 (1998);
82	Mccarty et al., "Sequence Required for Coordinate Induction of Adeno-Associated Virus p.19 and p.40 Promoters by Rep Protein," <i>J. Virol.</i> , 65:2936-2945 (1991);
83	McPherson et al., "Human Cytomegalovirus Completely Helps Adeno-Associated Virus Replication," <i>Virol.</i> 147:217-222 (1985);
84	Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," <i>Nucl. Acids. Res.</i> 18:5322 (1990);
85	Muzyczka, "Use of Adeno-Associated Virus as a General Transduction Vector for Mammalian Cells," <i>Curr. Top. Microbiol. Immunol.</i> , 158:97-129 (1992);
86	Naki et al., <i>Blood</i> 91:1-9 (1998); Reference could not be obtained at this time. Will provide a copy at a later date should the Examiner desire a copy.
87	Nambair et al., "Total Synthesis and Cloning of a Gene Coding for the Ribonuclease S Protein," <i>Science</i> 223: 1299-1301 (1984);
88	<i>Remington's Pharmaceutical Sciences</i> 18 th ed., Easton, Pa; Mack Pub. Co. (1990); Reference could not be obtained at this time. Will provide a copy of the Title and copyright pages at a later date should the Examiner desire a copy
89	Samadani et al., "Identification of a Transthyretin Enhancer Site That Selectively Binds the Hepatocyte Nuclear Factor-3 β Isoform," <i>Gene Expression</i> 6:23-33 (1996);
90	Sambrook et al., <i>Molecular Cloning, a Laboratory Manual</i> , Cold Spring Harbor Laboratories, New York (1989) (Title and Copyright Pages Only);

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91	Samulski et al., "helper-Free Stocks of Recombinant Adeno-Associated Viruses; Normal Intergration Does Not Require Viral Gene Expression," <i>J. Virol.</i> , 63:3822-3828 (1989);
92	Sanberg et al., XXth Int. Congress of the World Fed. Of Hemophilia (1992); Reference could not be obtained at this time. Will provide a copy at a later date should the Examiner desire a copy.
93	Schlehofer et al., "Vaccinia Virus, Herpes Simplex Virus, and Carcinogens Induce DNA Amplification in a Human Cell Line and Support Replication of a Herpesvirus Dependent Parvovirus," <i>Virol.</i> 152:110-117 (1986);
94	Shelling and Smith, "Targeted Integration of Transfected and Infected Adeno-Associated Virus Vectors Containing the Neomycin Resistance Gene," <i>Gene Ther.</i> , 1:165-169 (1994);
95	Shigekawa et al., "Electroporation of Eukaryotes and Prokaryotes: A General Approach to the Introduction of Macromolecules into Cells," <i>BioTechn.</i> 6:742-751 (1988);
96	Snyder, <i>Current Protocols in Genetics</i> , Chapter 12, John Wiley and sons (1997); Reference could not be obtained at this time. Will provide a copy at a later date should the Examiner desire a copy.
97	Thomson et al., "Human Herpesvirus 6 (HHV-6) is a Helper Virus for Adeno-Associated Virus Type 2 (AAV-2) and the AAV-2 rep Gene Homologue in HHV-6 Can Mediate AAV-2 DNA Replication and Regulate Gene Expression," <i>Virol.</i> , 204:304-331 (1994);
98	Tooele et al., "Molecular cloning of a cDNA encoding human antihemophilic factor," <i>Nature</i> 312:342-347 (1984);
99	Uetsuki et al., "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor - 1 α ," <i>J. Biol. Chem.</i> , 264:5791 (1989);
100	Vehar et al., "Structure of Human factor VIII," <i>Nature</i> 312:337-342 (1984);
101	Vincent et al. "Replication and Packaging of HIV Envelope Genes in a Novel Adeno-Associated Virus Vector System," in <i>Vaccines 90</i> , pp. 353-359, Cold spring Harbor Laboratory Press (1990);
102	Voss, et al., "The role of enhancers in the regulation of cell-type-specific transcriptional control," <i>Trends Biochem. Sci.</i> , 11:287-289 (1986);
103	Wood et al., "Expression of active human factor VIII from recombinant DNA clones," <i>Nature</i> 312:330-337 (1984);
104	Yan et al., "Distinct positive and negative elements control the limited hepatocyte and choroid plexus expression of transthyretin in transgenic mice." <i>EMBO J.</i> 9:869-878 (1990);
105	Yonemura et al., "Efficient production of recombinant human factor VIII by the expression of their heavy and light chains," <i>Prot. Engineer.</i> , 6:669-674 (1993).
106	Young et al., "Adeno-Associated Virus - an Extreme State of viral Defectiveness," <i>Prog. Med. Virol.</i> , 25:113-132 (1979)
107	Zhou et al., "Adeno-Associated Virus 2-Mediated High Efficiency Gene Transfer Into Immature and Mature Subsets of Hematopoietic Progenitor Cells in Human Umbilical Cord Blood," <i>J. Exp. Med.</i> , 179: 1867-1875 (1994)
108	Conrad et al., "Safety of single-dose administration of an adeno-associated virus (AAV)-CFTR vector in the primate lung." <i>Gene Ther.</i> , 3:658-668 (1996)

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109	Byrnes et al., "Immunological Instability of Persistent Adenovirus Vectors in the Brain: Peripheral Exposure to Vector Leads to Renewed Inflammation, Reduced Gene Expression, and Demyelination," <i>J. Neuroscience</i> 16:3045-3055 (1996)
110	Yang et al., "Immune response to viral antigens versus transgene product in the elimination of recombinant adenovirus-infected hepatocytes in vivo," <i>Gene Ther.</i> , 3:137-144 (1996)
111	Yang, et al., Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy," <i>Proc. Natl. Acad. Sci. USA</i> 91:4407-4411 (1994)
112	Kass-Eisler et al., "The impact of developmental stage, route of administration and the immune system on adenovirus-mediated gene transfer," <i>Gene Ther.</i> , 1: 395-402 (1994)
113	Mizuno et al., "Adeno-associated Virus Vector Containing the Herpes Simplex Virus Thymidine Kinase Gene Causes Complete Regression of Intracerebrally Implanted Human Gliomas in Mice, in Conjunction with Ganciclovir Administration," <i>Jpn. J. Cancer Res.</i> , 89:76-80 (1998)
114	Verma and Sornia, "Gene Therapy - promises, problems and prospects," <i>Nature</i> 389:239-242 (1997)
115	Kaplitt et al., "Viral Vectors for Gene Delivery and Expression in the CNS," <i>In Methods: A Companion to Methods in Enzymology</i> 10: 343-350 (1996)
116	Anderson, "Human gene therapy," <i>Nature</i> 392:25-30 (1998)
117	Jooss et al., "Transduction of Dendritic Cells by DNA Viral Vectors Directs the Immune Response to Transgene Products in Muscle Fibers," <i>J. Virol.</i> , 72:4214-4223 (1998)
118	Rodriguez et al., "DNA Immunization with Minigenes: Low Frequency of Memory Cytotoxic T Lymphocytes and Inefficient Antiviral Protection Are Rectified by Ubiquitination," <i>J. Virol.</i> , 72:5174-5181 (1998)
119	Szomolanyi-Tsuda et al., "T-Cell-Independent Immunoglobulin G. Responses in Vivo are Elicited by Live-Virus Infection but Not by Immunization with Viral Proteins or Virus-Like Particles," <i>J. Virol.</i> , 1998 72:6666-70
120	Ulmer et al., "Protective CD4+ and CD8+ T Cells against Influenza virus Induced by Vaccination with Nucleoprotein DNA," <i>J. Virol.</i> , 72: 5648-5653 (1998)
121	Tsuji et al., "Recombinant Sindbis Viruses Expressing a Cytotoxic T-Lymphocyte Epitope of a Malaria Parasite or of Influenza Virus Elicit Protection Against the Corresponding Pathogen in Mice." <i>J. Virol.</i> , 72:6907-6910 (1998)
122	Yauch et al., "Role of Individual T-Cell Epitopes of Theiler's Virus in the Pathogenesis of Demyelination Correlates with the Ability to Induce a Th1 Response," <i>J. Virol.</i> , 72:6169-6174 (1998)
123	Xiao et al., "Efficient Lone-Term Gene Transfer into Muscle Tissue of Immunocompetent Mice by Adeno-Associated Virus Vector," <i>J. Virol.</i> , 70:8098-8108 (1996)

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<i>R</i>	124	4,965,199	10/23/90	Capon et al.			08/07/87
	125	5,843,742	12/01/98	Natsoulis et al.			09/08/95
	126	5,872,005	02/16/99	Wang et al.			05/12/95
	127	5,219,740	06/15/93	Miller et al.			02/13/87
	128	5,399,346	03/21/95	Anderson et al.			03/30/94
	129	5,225,347	07/06/93	Goldberg et al.			03/19/90
	130	4,722,848	02/02/88	Paoletti et al.			06/19/84
	131	5,436,146	07/25/95	Shenk et al.			06/21/93
	132	5,474,935	12/12/95	Chatterjee et al.			11/03/93
	133	5,587,308	12/24/96	Carter et al.			06/02/92
	134	5,658,785	08/19/97	Johnson			06/06/94
	135	5,861,314	01/19/99	Philip et al.			06/06/95
	136	5,693,531	12/02/97	Chiorini et al.			11/24/93
	137	5,677,158	10/14/97	Zhou et al.			06/07/95
	138	5,252,479	10/12/93	Zrivastava			11/08/91
<i>R</i>	139	5,580,703	12/03/96	Kotin et al.			09/20/94

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P	140	5,658,776	08/19/97	Flotte et al.			06/07/95
P	141	5,622,856	04/22/97	Natsoulis			08/03/95

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P	142	WO 88/09809	12/15/88	PCT				
	143	WO 89/03429	04/20/89	PCT				
	144	WO 92/03545	03/05/92	PCT				
	145	0 592 836	04/20/94	EP				
	146	WO 96/15777	05/30/96	PCT				
	147	WO 96/13698	05/09/96	PCT				
	148	WO 93/24641	12/09/93	PCT				
	149	WO 95/07995	03/23/95	PCT				
P	150	WO 94/13788	06/23/94	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication, etc.)

P	151	Surosky et al, "Adeno-Associated Virus Rep Proteins Target DNA Sequences to a Unique Locus in the Human Genome," <i>J. Virol.</i> 71:7951-7959 (1997)	
	152	Miller and Rosman, "Improved Retroviral Vectors for Gene Transfer and Expression," <i>BioTechn.</i> 7:980-990 (1989)	
	153	Miller, "Retrovirus Packaging Cells," <i>Human Gene Ther.</i> 1:5-14 (1990)	
P	154	Scarpa et al., "Characterization of Recombinant Helper Retroviruses from Moloney-Based Vectors in Ecotropic and Amphotropic Packaging Cell Lines," <i>Virol.</i> 180:849-852 (1991)	

EXAMINER

P. J. L.

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155	Burns et al., "Vesicular stomatitis virus G Glycoprotein pseudotyped retroviral vectors: Concentration to very high titer and efficient gene transfer into mammalian and nonmammalian cells," <i>Proc. Natl. Acad. Sci. USA</i> 90:8033-8037 (1993)
156	Boris-Lawrie and Temin, "Recent advances in retrovirus vector technology," <i>Curr. Opin. Gen. Dev.</i> 3:102-109 (1993)
157	Haj-Ahmad and Graham, "Development of a Helper-Independent Human Adenovirus Vector and its Use in the Transfer of the Herpes Simplex virus Thymidine Kinase Gene," <i>J. Virol.</i> 57:267-274 (1986)
158	Bett et al., "Packaging Capacity and Stability of Human Adenovirus Type 5 Vectors," <i>J. Virol.</i> 67: 5911-5921 (1993)
159	Mittereder et al., "Evaluation of the Efficacy and Safety of <i>In Vitro</i> , Adenovirus-mediated Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator cDNA," <i>Human Gene Ther.</i> 5: 717-729 (1994)
160	Seth et al., "Mechanism of Enhancement of DNA Expression Consequent to Cointernalization of a Replication-Deficient Adenovirus and Unmodified Plasmid DNA," <i>J. Virol.</i> 68: 933-940 (1994)
161	Barr et al., "Efficient catheter-mediated gene transfer into the heart using replication-defective adenovirus," <i>Gene Ther.</i> 1: 51-58 (1994)
162	Berkner et al., "Development of Adenovirus Vectors for the Expression of Heterologous Genes," <i>BioTechn.</i> 6:616-629 (1988)
163	Rich et al., "Development and Analysis of Recombinant Adenoviruses for Gene Therapy of Cystic Fibrosis," <i>Human Gene Ther.</i> 4:461-476 (1993)
164	Berne and Bohenzky, "Adeno-associated Viruses: An Update," <i>Adv. Virus Res.</i> 32: 243-307 (1987)
165	Mackett et al., "The Construction and Characterization of Vaccinia Virus Recombinants Expressing Foreign Genes," in <i>DNA Cloning: A Practical Approach Vol. II</i> , Glover et al (ed.), pp. 191-211, Oxford; New York: IRL Press (1995)
166	Han et al., "Inhibition of Moloney murine leukemia virus-induced leukemia in transgenic mice expressing antisense RNA complementary to the retroviral packaging sequences," <i>Proc. Natl. Acad. Sci. USA</i> 88: 4313-4317 (1991)
167	Uhlmann and Peyman, "Antisense Oligonucleotides: A New therapeutic Principle," <i>Chem. Rev.</i> 90:543-584 (1990)
168	Helene and Toulme, "Specific regulation of gene expression by antisense, sense and antigene nucleic acids," <i>Biochim. Biophys. Acta</i> 1049: 99-125 (1990)
169	Agrawal et al., "Oligodeoxynucleoside phosphoroamidates and phosphorothioates as inhibitors of human immunodeficiency virus," <i>Proc. Acad. Natl. Sci. USA</i> 85: 7079-7083 (1988)
170	Heikkila et al., "A c-myc antisense oligodeoxynucleotide inhibits entry into S phase but not progress from G ₀ to G ₁ ," <i>Nature</i> 328: 445-449 (1990)
171	Samulski et al., "Targeted integration of adeno-associated virus (AAV) into human chromosome 19," <i>EMBO J.</i> 10: 3941-3950 (1991)
172	Kotin et al., "Characterization of a preferred site on human chromosome 19q for integration of adeno-associated virus DNA by non-homologous recombination," <i>EMBO J.</i> 11: 5071-5078 (1992)
173	Weitzman et al., "Adeno-associated virus (AAV) Rep proteins mediate complex formation between AAV DNA and its integration site in human DNA," <i>Proc. Natl. Acad. Sci. USA</i> 91: 5808-5812 (1994)

EXAMINER

DATE CONSIDERED

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APPLICANT - Couto, et al.

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174	Walz and Schlefer, "Modification of Some Biological Properties of HeLa Cells Containing Adeno-Associated Virus DNA Integrated into Chromosome 17," <i>J. Virol.</i> 66: 2990-3002 (1992)
175	Hu and Davidson, "The Inducible lac Operator-Repressor System is Functional in Mammalian Cells" <i>Cell</i> 48: 555-566 (1987)
176	Urlaub et al., "Isolation of Chinese hamster cell mutants deficient in dihydrofolate reductase activity," <i>Proc. Natl. Acad. Sci. USA</i> 77: 4216-4220 (1980)
177	Ringold et al., "Co-Expression and Amplification of Dihydroxofolate Reductase cDNA and the <i>Escherichia coli</i> XGPRT Gene in Chinese Hamster Ovary Cells," <i>J. Mol. Appl. Gen.</i> 1: 165-175 (1981)
178	McVey et al., "Properties of the DNA-Binding Domain of the Simian Virus 40 Large T Antigen," <i>Mol. Cell. Biol.</i> 9: 5525-5536 (1989)
179	Finney and Bishop, "Predisposition to Neoplastic Transformation Caused by Gene Replacement of H-ras1," <i>Science</i> 260: 1524-1527 (1993)
180	Trapnell, "Adenoviral vectors for gene transfer," <i>Adv. Drug Delivery Rev.</i> 12: 185-199 (1993)
181	Michael et al., "Binding-incompetent Adenovirus Facilitates Molecular Conjugate-mediated Gene Transfer by the Receptor-mediated Endocytosis Pathway," <i>J. Biol. Chem.</i> 268: 6866-6869 (1993)
182	Wagner et al., "Coupling of adenovirus to transferrin-polylysine/DNA complexes greatly enhances receptor-mediated gene delivery and expression of transfected genes," <i>Proc. Natl. Acad. Sci. USA</i> 89: 6099-6103 (1992)
183	Mackett et al., "General Method for Production and Selection of Infectious Vaccinia Virus Recombinants Expressing Foreign Genes," <i>J. Virol.</i> 49: 857-864 (1984)
184	Fuersst et al., "Eukaryotic transient-expression system based on recombinant vaccinia virus that synthesizes bacteriophage T7 RNA polymerase," <i>Proc Natl. Acad. Sci. USA</i> 83: 8122-8126 (1986)
185	O'Gorman et al., "Recombinase-Mediated Gene Activation and Site-Specific Integration in Mammalian Cells," <i>Science</i> 251: 1351-1355 (1991)
186	Van Deursen et al., "Cre-mediated site-specific translocation between nonhomologous mouse chromosomes," <i>Proc Natl. Acad. Sci. USA</i> 92: 7376-7380 (1995)
187	Srivastava et al., "Nucleotide Sequence and Organization of the Adeno-Associated Virus 2 Genome," <i>J. Virol.</i> 45: 555-564 (1983)
188	Berns, "Parvovirus Replication," <i>Microbiol. Rev.</i> 54: 316-329 (1990)
189	Ketner et al., "Efficient manipulation of the human adenovirus genome as an infectious yeast artificial chromosome clone," <i>Proc Natl. Acad. Sci. USA</i> 91: 6186-6190 (1994)
190	Cukor et al., "Biology of Adeno-Associated Virus," in <i>The Parvoviruses</i> , Berns (ed.), pp. 33-39, New York, Plenum Press (1984)
191	Kotin et al., "Site-specific integration by adeno-associated virus," <i>Proc Natl. Acad. Sci. USA</i> 87: 2211-2215 (1990)
192	Im et al., "The AAV Origin Binding Protein Rep68 is an ATP-Dependent Site-Specific Endonuclease with DNA Helicase Activity," <i>Cell</i> 61: 447-457 (1990)

EXAMINER

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

193	Wu et al. (eds.), Ghosh and Bachhawat, "Targeting of Liposomes to Hepatocytes," in <i>Liver Diseases. Targeted Diagnosis and Therapy Using Specific Receptors and Ligands</i> , p. 97-103, Marcel Dekker, Inc., New York (1991)
194	Snyder et al., "Features of the Adeno-Associated Virus Origin Involved in Substrate Recognition by the Viral Rep Protein," <i>J. Virol.</i> 67: 6096-6104 (1993)
195	Chiorini et al., "Biologically Active Rep Proteins of Adeno-Associated virus Type 2 Produced in Fusion Proteins in <i>Escherichia coli</i> ," <i>J. Virol.</i> 68: 797-804 (1994)
196	Chiorini et al., "Sequence Requirements for Stable Binding and Function of Rep68 on the Adeno-Associated Virus Type 2 Inverted Terminal Repeats," <i>J. Virol.</i> 68: 7448-7457 (1994)
197	Philip et al., "Efficient and Sustained Gene Expression in Primary T Lymphocytes and Primary and Cultured tumor Cells Mediated by Adeno-Associated Virus Plasmid DNA complexed to Cationic Liposomes," <i>Mol. Cell. Biol.</i> 14: 2144-2418 (1994)
198	Xiao et al., "Adeno-associated virus (AAV) vectors for gene transfer," <i>Adv. Drug Del. Rev.</i> 12: 201-215 (1994)
199	Page et al., "Recombinant AAV Vectors: Viral and Liposome Mediated Transfection of Recombinant AAV Genome Leads to High Efficiency Gene Transfer into Primary Cells," <i>J. Cell. Biochem. Suppl.</i> 18A: 228 (1994)
200	Nahreini et al., "Cloning and Integration of DNA fragments in human cells via the inverted terminal repeats of the adeno-associated virus 2 genome," <i>Gene</i> 119: 265-272 (1992)
201	Srivastava et al., "Construction of a recombinant human parvovirus B19: Adeno-associated virus 2 (AAV) DNA inverted terminal repeats are functional in an AAV-B19 hybrid virus," <i>Proc Natl. Acad. Sci. USA</i> 86: 8078-8082 (1989)
202	Hermonat and Muzyczka, "Use of adeno-associated virus as a mammalian DNA cloning vector: Transduction of neomycin resistance into mammalian tissue culture cells," <i>Proc Natl. Acad. Sci. USA</i> 81: 6466-6470 (1984)
203	McLaughlin et al., "Adeno-Associated Virus General Transduction Vectors: Analysis of Proviral Structures," <i>J. Virol.</i> 62: 1963-1973 (1988)
204	Yang et al., "Characterization of Cell Lines that Inducibly Express the Adeno-Associated Virus Rep Proteins," <i>J. Virol.</i> 68: 4847-4856 (1994)
205	Marshall, "Gene Therapy's Growing Pains," <i>Science</i> 269: 1050-1055 (1995)

DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Place of Publication, etc.)

1	Connelly, et al., "Complete Short-Term Correction of Canine Hemophilia A by In Vivo Gene Therapy," <i>Blood</i> 88(10):3846-3853 (1996)
2	Connelly et al., "Sustained Phenotypic Correction of Murine Hemophilia A by In Vivo Gene Therapy," <i>Blood</i> 91(9):3273-3281 (May 1, 1998)
3	Lozier, et al., "Gene Therapy and the Hemophilias," <i>JAMA</i> 271(1):47-51 (1994)
4	Snyder et al., "Persistent and Therapeutic Concentrations of Human Factor IX in Mice after Hepatic Gene Transfer of Recombinant AAV Vectors," <i>Nature Genetics</i> 16:270-276 (July 1997)
5	Zatloukal et al., "In vivo production of human factor VIII in mice after intrasplenic implantation of primary fibroblasts transfected by receptor-mediated, adenovirus-augmented gene delivery," <i>Proc Natl. Acad. Sci. USA</i> 91:5148-5152 (1994)

EXAMINER

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